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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,398	07/17/2000	MELENIE J MURPHY	124-781	4847

7590 12/20/2001

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,398	MURPHY ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Oct.12, 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-3,21-28 and 37* is/are withdrawn from consideration. 35

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-20 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 6 is acknowledged. The traversal is on the ground(s) that there is unity between the group II and claims 1and 2, thus the rejection should be withdrawn. This is not found persuasive because Group I involves different reagents, when compared with the other groups, thus there is no corresponding technical feature between Group I and any other group. Group II determines the susceptibility of bacteria to a reagent. This method uses lysed bacteria and exposes it to a reagent. The method also comprises a separation and incubation step. Group I does not comprise a similar step or determine similar results, therefore Group II has different technical features than group I.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). However, the abstract from the international application will be used in the instant application.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4-20 and 36 recites the limitation "the adenylate kinase", "the culture", and "the results in the claims. There is insufficient antecedent basis for ~~this~~ these limitations in the claim.

Claims 4-20 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: There is no contact step that contacts adenylate kinase ~~which~~ with a detection agent. There is detection step that recites how the adenylate kinase is detected. There is no correlation step that correlates the lysed bacteria with the method for determining the susceptibility of the bacteria. Method steps must be positively recited. See *Ex parte Erlich* 3 USPQ 101.

5. Claim 36 is rejected for being vague and indefinite for the recitation of "..hereinbefore described with reference to the Examples." The metes and bounds of the claim cannot be ascertained with such a claim. It is unclear what method steps applicant intends to embrace. The language is not as precise as it could be in view of the specification. Applicant is asked to clearly state what applicant is intending to claim.

Clarification is required to overcome the rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4-20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squirrell (WO 96/02666) in view of Sanders (WO 94/064931.

Squirrell teaches a method for determining the presence and/or amount of a microorganism and its intracellular material in a sample characterized by exposing the sample to a specific bind agent that has been immobilized upon a solid surface, thus allowing capture, the adenylate kinase activity ~~assed~~ assessed and the released such that a further sample of test material may be analyzed (page 3). The invention relates to improvements in which adenylate kinase activity is used as a label or marker for microorganism capture techniques (page 2). The adenylate kinase activity can work with colorimetric assays, conventional capture assays and other well-known immunoassays (page 2-3). Using the adenylate kinase format with adenylate kinase and ATP depleted reagent, the number of microorganisms present in a sample can be determined (page 3). Targeting adenylate kinase instead of ATP allows for higher sensitivity detection not seen with other methods (page 1). The adenylate kinase system allows for a linear correlation between the protein and the bacterial count (page 2). The methods also describe single reagent use with the adenylate kinase testing methods (page 7). Contaminants can affect the adenylate kinase production (page 8),

thus acting as an antibiotic and making the bacteria susceptible to death. In order to distinguish between target cells and other cells, separate assays can be run treating with a nonionic detergent capable of disrupting cells (page 10). Other reagents capable of cell ~~lyses~~ lysis are also taught (page 10). However, Squirrell does not teach lysis at a different point in time as a similar culture.

Sanders teaches a method for ~~detect~~ detection, identification and/or quantification of bacteria. The invention is based upon the occurrence of release of cell contents upon damage, i.e., lysis of cell walls of bacteria when new phage particles are released at the end of the phage replication cycle (page 2). The phage allows for fast and sensitive results when compared with non-phage systems. The method provides for the detection of specific bacteria that does not require insertion of the lux gene into the phage genome (page 2). The method has more readily realized potential for specific and rapid detection of almost any bacteria in any environment (page 2). The method comprises incubating the material or bacteria derived with bacteriophage selected for the ability to specifically infect target organisms. The release of cellular contents and the incubation step is carried out in bacterial support medium (page 3). The enrichment of the bacteria is preferably carried out with a culturing selective medium favoring growth of the target bacteria (page 4).

Therefore, it would have been obvious at the time of applicants invention to have used the bacteriophage particles released at the end of phage replication as taught by Sander et al., in the method of determining susceptibility of bacteria as taught by Squirrell, because Sanders et al., teaches that the phages are only limited by the

availability of phage types, and provides faster and more sensitive results when compared with non-phage systems.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na A Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
December 17, 2001

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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